a **science group** company

Technology Sciences Group Inc.

1150 18th St. NW, Suite 1000
Washington, DC 20036
Direct: (202) 828-8969
Email: casey.pehrson@tsgconsulting.com

Casey M. Pehrson
Regulatory Consultant

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460
Submitted electronically

March 26, 2020

Re: FOIA Request for Sinanen Zeomic Co. LTD
EPA Co. No.: 71227

To Whom It May Concern,

Technology Sciences Group Inc., on behalf Sinanen Zeomic Co. LTD hereby submits this FOIA Request to obtain a copy of the **RASBB Memorandum entitled "Silver Zeolite X. Evaluation of Sinanen's response to the Agency memorandum concerning waiver requests, test substance identification, and data bridge for toxicology studies supporting registration applications for Zeomic Type HJ and HW Silver Zeolite X Products" dated October 13, 2011.** This RASBB Memorandum is referenced in the attached Memorandum dated December 13, 2011. Sinanen Zeomic Co. LTD is the owner of the associated registrations.

Sinanen would like a digital copy of the files for the aforementioned products sent to authorized agent Abigail Wacek of Technology Sciences Group Inc. (1150 18th Street, NW, Suite 1000, Washington DC 20036) at Abigail.wacek@tsgconsulting.com.

Please do not hesitate to contact me with any questions at (202) 828-8996 or via e-mail: casey.pehrson@tsgconsulting.com.

Sincerely,

Casey Pehrson
Regulatory Consultant

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)
December 13, 2011

DP BARCODE: 395095

MRID : NA

SUBJECT: This reviews applies to these two products

EPA File Symbol	Name
87731-R	Zeomic Type HJ Silver Zeolite X®
87731-E	Zeomic Type HW Silver Zeolite X®

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
072501	7779-88-8	Silver

TEST LAB: Eurofins|Product Safety Labs and Sinanen Company Lab

SUBMITTER: Sinanen Zeomic Co. LTD
(formerly known as Sinanen Company, LTD)

GUIDELINE: Product Chemistry Groups A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVAL DATE: December 13, 2011

COMMENT: This review is written to address the registrants response to issues identified in a product chemistry review dated July 29, 2011 for products previously identified by EPA File Symbol 71227-I and 71227-O. Subsequently these two products are reassigned from Sinanen company LTD (# 71227) to Sinanen Zeomic Co LTD (# 87731), so that these products are now identified by EPA File Symbols 87731-R and 87731-E.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)
December 13, 2011

MEMORANDUM

SUBJECT: Applies to these two products

EPA File Symbol	Name
87731-R	Zeomic Type HJ Silver Zeolite X®
87731-E	Zeomic Type HW Silver Zeolite X®

DP Barcode: 395095

CODE: (A540) New Product Registration

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/ Martha Terry
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Sinanen Zeomic Co LTD

PRODUCT FORMULATION FROM LABEL FOR EACH

87731-R Zeomic Type HW Silver Zeolite X®		**87731-E Zeomic Type HJ Silver Zeolite X®**	
Active Ingredient(s):	% by wt.	Active Ingredient(s):	% by wt.
Silver	0.5	Silver	2.2
Other Ingredient(s):	99.5	Other Ingredient(s):	97.8
Total:	100.00	Total:	100.00

BACKGROUND:

The registrant previously submitted data to address the product chemistry requirements for the registration of their new end use products EPA File Symbol 71227-I Zeomic Type HW Silver Zeolite X and EPA File Symbol 71227-0 Zeomic Type HJ Silver Zeolite X.

These are end use products used as a preservative and bacteriostatic additive for the manufacture of polymer, plastic, latex, composite building materials products, and a number of other materials. Its mode of action is described as resulting from the effects of release of silver ions from a particulate Zeolite X carrier. These products do not currently make any public health claims nor are they to be used in manufactured products involving direct or indirect food or drinking water contact.

They were previously reviewed and found to have technical issues regarding the identity of the product. The purpose of this product chemistry review is to evaluate whether or not these issues have been addressed.

Concurrently, along with the review of the product chemistry submission there were additional reviews conducted by the Antimicrobials Division Risk Assessment and Science Support Branch (RASSB) with respect to the nature of the active ingredient, whether the silver active ingredient acts by itself, or acts in conjunction with the "inert" carrier as a unique new active ingredient. Included was review of the Zeolite X inert carrier and data bridging for toxicology studies to support the registration applications for these products.

This review package included

1. A letter from the registrant dated August 1, 2011.
2. Copy of a RASBB memorandum entitled, "Silver Zeolite X. Evaluation of Sinanen's response to the Agency memorandum concerning waiver requests, test substance identification, and data bridging for toxicology studies supporting registration applications for Zeomic Type HJ and HW Silver Zeolite X Products dated October 13, 2011. See Table 1 from this document below in Findings.
3. Revised Confidential Statements of formula dated December 7, 2011. These include a Basic CSF (Type N), Alternate (Type D), and Alternate (Type H) for both products.
4. In addition, previous product chemistry reviews as well as all documents which were used for the last product chemistry review (July 29, 2011) were available for reference.

FINDINGS:

The findings here are organized around the (5) recommended item listed in the past chemistry review for both of these products.

Item #1: *"In order to support product types identified as type D and H, alternate CSFs must be provided which describe the composition and certified limits specific to each."*

CSFs for alternate formulations were provided by the registrant to describe the composition the of the three intentionally produced alternate formulations for each of these two products. The Basic formulation is identified as Type N, with two alternate types D and H. They have different amounts of water to allow better compatibility with different materials.

Status: Item #1 is considered as being resolved.

Item #2: *"In order for these to be approved as alternates under this registration, data must be provided. This validates that they have the same physical and chemical properties and conform to the same certified limits as the basic product."*

All alternate CSFs observe conventional requirements that the nominal concentrations of silver and the certified limits are the same as for the basic CSF. The amount of inert carrier (Zeolite X) varies to make up the difference. Considering the available binding capacity of the Zeolite and the necessity to use the product with a range of different materials, any differences in some physical and chemical properties (pH, density etc) would be minimal.

Status: Item #2 is considered as being resolved.

Item #3: *"The product chemistry studies which are expected to vary based on moisture content would be: density (pour and tap), pH, and particle size distribution. Note that if an aqueous media is used for particle size analysis one might expect that less hydrated types would hydrate to a common hydration level which would obscure the size differences. Therefore, in order to accurately differentiate differences in the particle size, a medium or method which does not change the hydration level of the material must be used".*

The measured particle size could vary depending on the degree of hydration of the product, it is expected that the "dryer" alternates would approach the size of the basic formulation when measured in an aqueous media. It is expected that the difference would be marginal.

Status: Item #3 is considered as being resolved.

Issue #4: *"It may be considered that it is outside the scope of routine product chemistry to be (so) concerned about an inert. In the case of this product the composition and structure of the inert is expected to have a significant effect on the release of the silver ions depending on the environment. The specific information regarding the regular structure, pore size, release rate and capacity has not been provided. Such information is normally requested on a case basis by the Risk Assessment and Science Support Branch (RASSB) Staff."*

Resolution to #4: The following is an insert with a table of chemical and structural information as summarized in the RASSB memo. The rightmost column was completed by the registrant at the Agency's request. This table provides data which supports that the inert carrier Zeolite-X in these products is substantially identical to published data on this Zeolite. Also it addresses that through there are some general similarities between Zerolite X and Zeolite A, they are structurally different. The degree to which they can substitute for one another might depend on the application.

SUMMARY OF SUBMITTED INFORMATION

To permit the Agency to determine whether there is substantial similarity between Metal-Zeolites A and X, Sinanen Co. has submitted information to address the deficiencies cited in the 8/8/11 EPA memorandum. This consisted of several structural and physical properties and a comparison of the acute toxicity studies conducted on three of Sinanen's registered Zeolite A products and their two pending Zeolite X products. The properties are presented in Table 1 (excerpted from the 8/8/11 EPA review) with Sinanen's new information in shaded cells. The acute toxicity comparison in Table 2 is taken from TSG's 8/1/11 letter.

Table 1. Comparison of Zeolite A and X structural and physical properties.

Property	Zeolite A	Zeolite X (published)	Zeolite X (Sinanen)[b]
Formula of periodic building unit	$Na_{12}[(AlO_2)_{12}(SiO_2)_{12}]$ $\cdot 27H_2O$	$Na_{86}[(AlO_2)_{86}(SiO_2)_{106}]$ $\cdot 264H_2O$	$Na_{12}(AlO_2)_{12}(SiO_2)_{12}\cdot 27H_2O$ or $Na_2O\cdot Al_2O_3\cdot 2.4SiO_2$
Pore opening of the Na^+ form	4.2 Å	8 Å	7.2 Å
IZA Framework Type Code	LTA	FAU	FAU
Crystal system	Cubic	Cubic	Cubic
No. β-cages/cube face[a]	Four	Six	Six
Channel sides	8-ring	12-ring	12-ring
Cation Exchange Capacity (CEC)	5.48 meq/g	4.73 meq/g	4.7 meq/g
Cavity diameter	11.4 Å	13 Å	13 Å

[a]A β-cage is a 14-faced 3-dimensional structure having eight 6-sided faces and six 4-sided faces. Its chemical composition as a mineral in the sodium form is $Na_6[Al_6Si_6O_{24}]$.
[b]Information in shaded cells is from the 8/1/11 TSG letter on behalf of Sinanen Zeomic Co., Ltd.

Comment: The formulation of periodic building units for Zeolite X (Sinanen) is most likely in error. It is virtually impossible for Zeolite X to have the same Periodic building unit formula as Zeolite A yet have a different framework structure, no empirical data was provided. Unless proven otherwise the formula of the building unit will be assumed to be that published for Zeolite X.

Status: Item #4 is considered as being resolved.

Issue #5: *"Data must be submitted to the Registration Division Inerts Branch in order to assign a specific PC Code for Zeolite X (CAS # 68989-23-1) and the CSF revised to include the correct CAS #"*

Resolution to #5: It was determined that sufficient data was submitted to support the addition of the Zeolite X to the Agency's inert database and assign a unique PC Code in association with its individual CAS#. This PC Code will identify this inert on future CSFs as necessary.

Status: Item #5 is considered as being resolved

CONCLUSION:

The basic and two alternate CSFs dated December 7, 2011 are acceptable. On the basis of the data and deliberations over the issues relative to the identity of the active ingredient as well as the inert carrier the product chemistry concerns as previously identified have been resolved.